K070920

FUJIFILM Medical Systems, USA, Inc.
Fuji IP Cassette Type PC 510(k)

510(k) Summary

MAY 22 2007

Date Prepared

March 29, 2007

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
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Contact: Debra A. Peacock

Trade Name, Common Name, Classification

The device trade name is:

Fuji IP Cassette Type PC

Common or classification names:

Classification Name: An accessory to a medical charged particle radiation therapy system.

Common Name: Portal imaging cassette or radiographic cassette.

Predicate Device

Fuji identifies the predicate devices as follows:

Device	510(k)
Agfa CR RT1.0 Low Dose Cassette	K042779
Kodak EC-L Film Cassette	K960834

Description of the Device

The Fuji IP Cassette Type PC will be used as an accessory to medical charged particle radiation therapy systems providing radiation therapy (portal localization) imaging. The Fuji IP Cassette Type will be used with a FDA-cleared radiation treatment linear accelerator or cobalt 60 unit. The Type PC cassette is a digital replacement technology for conventional film/cassette imaging systems. This cassette is appropriate to accommodate energies up to 18 MV and higher.

Due to the high dose rates associated with this oncology indication, a 0.5 mm lead (Pb) absorber was added to the front of the cassette. In addition, a compression plate was added to the back of the cassette to place the imaging plate (IP) in contact with the lead cassette front during exposure. The compression mechanism was developed to maintain contact between the cassette front and IP during exposure to ensure maximum resolution and contrast.

Instead of film, a Fuji Imaging Plate (IP) is loaded into the cassette for exposure. Before exposure, the compression plate is engaged by moving the thumb sliders on the cassette to the EXPOSE position. After exposure, the compression plate is returned to its retracted position by moving the slide button from the EXPOSE position to the READER position. The cassette is then inserted into the appropriate Fuji image reader for scanning. After processing the IP in the

CR reader, the IP is erased and returned to the cassette for reuse. No new software modifications to the CR reader or workstation are needed for this indication.

The imaging plate is processed in the CR reader according to exam and user-specified parameters. Images are processed using currently-cleared MFP image processing with FNC applied. The resulting image may be displayed on a cleared CRT or LCD monitor, printed by a hard copy device onto film, or output to a cleared diagnostic workstation, optical disk file, PACS or therapy planning workstations that accepts DICOM images. FDA has cleared Fuji's imaging plate, image readers, and image processing applications in previous 510(k)s.

Note: Fuji Imaging Plates (IP) belonging to the Type ST (Standard) family, are to be used for this product.

The Fuji IP Cassette Type PC is offered in three sizes: 14"x17" (35 x 43 cm), 14"x14" (35 x 35 cm), and 10"x12" (25 x 30 cm).

Intended Use

The Fuji IP Cassette Type PC will be used as an accessory to megavoltage radiation therapy systems providing radiation therapy portal localization imaging and to aid in radiation therapy planning and quality control.

The Fuji IP Cassette Type PC and imaging plate is a digital replacement technology for conventional film/cassette imaging systems.

Technological Characteristics

The subject device is an accessory to a medical charged particle radiation therapy system. The concept of radiographic cassettes and digital imaging are not new; there are several cleared digital imaging cassettes used for this indication on the market. The radiographic technique is unchanged from that of a film/screen based portal imaging application.

In addition, the proposed device has the same technological characteristics as the above-listed predicate device.

Testing

The following tests were performed at West Virginia University Hospitals Radiation therapy department to compare Fuji's IP Cassette Type PC (digital) to Kodak's EC-L (screen film cassette).

Dose Linearity Bench Test: Testing was performed to confirm that the Fuji IP Cassette Type PC (Portal Imaging Cassette) has the desired log-linear response between dose and mean pixel value. Test result passed. The results also indicate that the response is independent of energy between 6 and 18 MV.

Varian PortalVision™: Contrast-Detail phantom Test Bench testing was performed on both cassettes to assess image quality through the use of a Varian PortalVision™ Phantom. Images were scored by three independent observers with the following results:

- 6MV- All three observers scored the Fuji CR image higher than the film image at the 6 MV energy range with a total score of 14.83 for the Fuji CR image vs. a 13.33 score for the Kodak film image.

- 18MV- Two out of three observers scored the Fuji CR image equal to or superior to the film image, with one observer scoring the Kodak film image 0.5 higher than the Fuji CR image. The average score for both systems is the same (9.0).

Varian Portal Vision™ Phantom with Anthropomorphic Phantom Test: Clinical testing was performed by placing the Varian PortalVision™ Phantom underneath the anthropomorphic phantom to obtain images in order to compare the standard port film cassette with Fuji's IP Cassette Type PC (portal imaging cassette).

Images were scored by three independent observers with the following results:

- Under the same exposure conditions at 6 MV, the Fuji CR image was scored equivalent (FCR judged slightly superior by 2 of 3 reviewers) to the Kodak film image when scoring the Varian PortalVision™ phantom with the superimposed anthropomorphic image.

- Under the same exposure conditions at 18 MV, the Fuji CR image is judged superior to the Kodak film image when scoring the Varian PortalVision™ phantom with the superimposed anthropomorphic image.

Sample images are enclosed in this 510(k) in Attachment 1.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 22 2007

Ms. Debbie Peacock
Regulatory Coordinator
FUJIFILM Medical Systems USA, Inc.
419 West Avenue
STAMFORD CT 06902

Re: K070920
Trade/Device Name: Fuji IP Cassette Type PC
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 29, 2007
Received: April 4, 2007

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE SUMMARY

Indications for Use

510(k) Number (if known): K070920

Device Name: **Fuji IP Cassette Type PC**

Indications for Use:

The Fuji IP Cassette Type PC will be used as an accessory to megavoltage radiation therapy systems providing radiation therapy portal localization imaging and to aid in radiation therapy planning and quality control.

The Fuji IP Cassette Type PC and imaging plate is a digital replacement technology for conventional film/cassette imaging systems.

Prescription Use	X	~~AND~~ / OR	Over-The-Counter-Use	
(Part 21 CFR 801 Subpart D)			(Part 21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070920